Appendix A Sample informed consent form

A phase 1/2a clinical trial to evaluate the safety and immunogenicity of ALVAC-HIV (vCP2438) and of MF59®- or AS01B-adjuvanted clade C Env protein, in healthy, HIV-uninfected adult participants

HVTN protocol number: HVTN 120

Site: [Insert site name]

Thank you for your interest in our research study. Please read this consent form or ask someone to read it to you. If you decide to join the study, we will ask you to sign or make your mark on this form. We will offer you a copy to keep. We will ask you questions to see if we have explained everything clearly. You can also ask us questions about the study.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

About the study

The HIV Vaccine Trials Network (HVTN) and [Insert site name] are doing a study to test HIV vaccines. HIV is the virus that causes AIDS.

About 160 people will take part in this study at multiple sites in Africa and the United States. The researcher in charge of this study at this clinic is [Insert name of site PI]. The United States National Institutes of Health (NIH) and the Bill & Melinda Gates Foundation are paying for the study.

1. **We are doing this study to answer several questions.**

   - Are the study vaccines safe to give to people?
   - Are people able to take the study vaccines without becoming too uncomfortable?
   - How do people's immune systems respond to different combinations and doses of the study vaccines? (Your immune system protects you from disease.)

2. **The study vaccines cannot give you HIV.**

   The study vaccines are not made from actual HIV. It is impossible for the study vaccines to give you HIV. Also, they cannot cause you to give HIV to someone else.

3. We do not know if the study vaccines will decrease, increase, or not change your chance of becoming infected with HIV if you are exposed to the virus.

Several studies have tested whether HIV vaccines can reduce the risk of getting HIV from another person. In some studies, people who got the vaccine seemed to have the *same* risk of getting HIV as people who did not get the vaccine. In one study, people who got the vaccine seemed to have a *lower* risk of getting HIV than people who did not get the vaccine. In other studies, some people who got the vaccine had a *higher* risk of getting HIV than people who did not get the vaccine.

This study differs from the studies in which people who got the vaccine had a higher or lower risk of getting HIV. The clinic staff can tell you about the differences.

We do not know whether the vaccines in this study will affect your risk of getting HIV from another person. The risk could be higher, lower, or unchanged. It is very important to avoid exposure to HIV during and after the study. We will tell you how to avoid HIV.

4. These study vaccines are experimental.

There are 3 study vaccines being tested in this study. They are all experimental vaccines. That means we do not know whether the vaccines will be safe to use in people, or whether they will work to prevent HIV infection. These vaccines are used only in research studies. The study vaccines are called ALVAC-HIV (vCP2438), Bivalent Subtype C gp120/MF59, and Bivalent Subtype C gp120/AS01$_B$. From here on, we will call them the ALVAC vaccine, the protein/MF59 vaccine, and the protein/AS01$_B$ vaccine, or the study vaccines.

The ALVAC vaccine

The ALVAC vaccine is made out of canarypox virus. Canarypox virus infects birds but cannot infect humans. This virus has small bits of man-made DNA inserted into it. DNA is a natural substance found in all living things, including people and some viruses. The canarypox virus helps get the DNA into the body's cells. The DNA then tells those cells to make small amounts of proteins that look like some of the ones found in HIV.

The Protein/MF59 vaccine:

The Protein/MF59 vaccine has man-made pieces of a protein found on the outside of HIV. These proteins will be mixed with an adjuvant. An adjuvant is a substance added to the vaccine to help the immune system respond better. In this study vaccine the adjuvant is called MF59. MF59 is commonly used in licensed flu vaccines in many countries. It has also been in other vaccines that have been given to over 50,000 people in research studies without causing any serious health problems.

The ALVAC vaccine and the Protein/MF59 vaccine combination is currently being given in South Africa in 2 studies named HVTN 100 and HVTN 702. For HVTN 100, 210 participants have received this vaccine combination. It is also being given in South Africa and other African countries in a study named HVTN 107. In addition, the Protein/MF59 is being given in 2 other studies named HVTN 111 and HVTN 108. Similar Protein vaccines have been given to more than 10,000 people in research studies. In these studies, the protein vaccines did not cause serious health problems.

The Protein/AS01$_B$ vaccine:

The Protein /AS01$_B$ vaccine has the same proteins used in the Protein/MF59 vaccine. However, these protein pieces are mixed with a different adjuvant called AS01$_B$. This adjuvant is also added to this vaccine to help the immune systems respond better.

The Protein/AS01$_B$ is also being given in one of the studies mentioned above, named HVTN 108. Similar vaccines have been given to over 1400 people in past studies. In these studies, the vaccines did not cause serious health problems.

This study will be the first time the ALVAC vaccine and the Protein/AS01$_B$ vaccine combination will be given to humans.

General risks of vaccines:

All vaccines can cause fever, chills, rash, aches and pains, nausea, headache, dizziness, and feeling tired. Vaccines can also cause pain, redness, swelling, or itching where you got the injection. Most people can still do their planned activities after getting a vaccine. Rarely, people have side effects that limit their normal activities or make them go to the doctor.

Rarely, a vaccine can cause an allergic reaction, including a rash, hives, or trouble breathing. Allergic reactions can be life-threatening. You should tell us if you have ever had a bad reaction to any injection or vaccine.

Rarely, people who have received vaccines with adjuvants have developed illnesses called autoimmune diseases. Autoimmune diseases have also occurred in people who have not been vaccinated. These diseases develop when immune cells that normally protect you from illness, attack your organs instead. Autoimmune diseases can be serious and can also be lifelong. They can involve for example your liver, kidneys, skin, joints, eyes, brain, as well as other parts of the body. Since no one knows for sure if vaccines with adjuvants might cause autoimmune diseases, we continue to monitor this situation closely.

Risks of the study vaccines:

The ALVAC vaccine and the Protein/MF59 vaccine:

In HVTN 100, the study vaccines have not caused serious health problems. About 3 out of 4 participants had mild or medium pain or tenderness on the arm where they got the injections. Three participants had severe arm pain after one of their injections. About 1 out of 7 participants had a small area of redness or hardening of the skin on the arm where they got the injections. These side effects did not bother most people much and all went away within a few days. Three participants had larger areas of redness or swelling (more than 10 cm in diameter) where they got the injection that bothered them. They were treated with prescription medications and the symptoms went away within a few days.

About 2 out of 3 participants felt weak or tired, or had a headache or body aches after an injection. A small number had nausea, chills, fever, or vomiting. These symptoms were mostly mild but in 4 participants their daily activities were affected (joint aches in 2, weakness/tiredness in 1 and headache in another person). All of these symptoms went away within a few days.

A few participants had one of these side effects after an injection: lump where they got the injection, itching where they got the injection or all over, lymph node swelling, stomach pain, diarrhea, dizziness, brief tingling around the mouth. These symptoms were all mild or medium and all went away within a few days.

Most of the symptoms participants had are common side effects of vaccines or of getting injections. We do not know yet which participants got the study vaccines and which got the placebo because the study is still "blinded", so we do not know if the study vaccines caused these side effects.

The Protein/AS01$_B$ vaccine:

The Protein/AS01$_B$ is being given in HVTN 108 and we will give you any important information that may come out of that study that may affect your health or your participation.

In studies with similar products some people had redness, swelling, pain, muscle tenderness, or itching in the area where they got the injection. Some people had headache, weakness, increased heart rate, and increased sensitivity to stimulation at the site of injection. A small number of people had flu-like symptoms, nausea, rash, vomiting, diarrhea, or swollen lymph nodes after getting an injection. A very small number of people had tiredness and difficulty sleeping. People who have these symptoms may only have a few of them and they usually go away within a few days.

There may be other risks of the study vaccines that we do not yet know about. We will tell you if we learn anything new that may affect your participation in the study.

Joining the study

5. **It is completely up to you whether or not to join the study.**

   Take your time in deciding. If it helps, talk to people you trust, such as your doctor, friends or family. If you decide not to join this study, or if you leave it after you have joined, your other care at this clinic and the benefits or rights you would normally have will not be affected.

   If you join this study, you may not be allowed to join other HIV vaccine or HIV prevention studies now or in the future. You cannot be in this study while you are in another study where you receive a study product. Also during the study, you should not donate blood or tissue.

   If you choose not to join this study, you may be able to join another study.

Site: Remove item 6 if you use a separate screening consent that covers these procedures.

6. **If you decide to join the study, we will screen you to see if you are eligible.**

   Screening involves a physical exam, HIV test and health history. A physical exam may include, but is not limited to:

   - Checking your weight, temperature and blood pressure
   - Looking in your mouth and throat
   - Listening to your heart and lungs
   - Feeling your abdomen (stomach and liver)

   We will also do blood and urine tests. These tests tell us about some aspects of your health, such as how healthy your kidneys, liver, and immune system are. We will also test you for Hepatitis B, Hepatitis C, and syphilis. We will ask you about medications you are taking. We will ask you about behaviors that might put you at risk for getting HIV. If you were assigned female sex at birth, we will test you for pregnancy. People who have had a hysterectomy or oophorectomy (removal of the uterus or ovaries, verified by medical records), are not required to have a pregnancy test. We will also ask if you have ever been allergic to eggs, egg products, or the antibiotic Neomycin.

   We will review the screening results with you. The screening results may show you are not eligible to join the study, even if you want to. Also, you might not be able to join if we have already enrolled enough people of your same sex.

Site: adapt the following section so it is applicable to the care available at your site

7. **If we find that you have a health problem during screening or during the study.**

   We will tell you about the care that we can give here for free.

   For the care that we cannot give, we will explain how we will help you get care elsewhere.

   We will not be able to pay for care for health problems that are unrelated to this study.

8. **If you were assigned female sex at birth and could become pregnant, you must agree to use birth control to join this study.**

Site: If you want to include Appendix B, Approved birth control methods (for sample informed consent form), in this consent form, paste it below and delete paragraph below.

You should not become pregnant during the study because we do not know how the study vaccines could affect the developing baby. You must agree to use effective birth control from 3 weeks before your first injection until 6 months after your last study injection. We will talk to you about effective birth control methods. They are listed on a handout that we will give to you.

Being in the study

If you meet the study requirements and want to join, here is what will happen:

9. **You will come to the clinic for scheduled visits about [#] times over 12 months.**

Site: Insert number of visits and range of visit lengths. (There is site-specific variation in screening protocols and in the number of possible follow-up visits between protocol-mandated visits).

Visits can last from [#] to [#] hours.

You may have to come for more visits if you have a laboratory test result or health issue.

We may contact you after the main study ends (for example, to tell you about the study results).

10. **We will give you [Site: Insert compensation] for each study visit you complete.**

    This amount is to cover the costs of [Site: Insert text]

Site: Insert any costs to participants (eg, birth control costs for female participants who could become pregnant).

US sites: Include the following paragraph:

Payments you receive for being in the study may be taxable. We may need to ask you for your Social Security number for tax reasons.

You do not have to pay anything to be in this study.

11. Not everyone in this study will get the study vaccines.

Everyone in this study will get some placebos. Placebos are substances that do not contain vaccine. Some people will get the study vaccines and also some placebos. Some people will get only placebos. We will compare the results from people who got the placebos with results from people who got the study vaccines.

The placebo for the study vaccines is saline solution. We do not expect the placebo to cause any health problems in people.

The clinic staff have no say in whether you get the study vaccines and/or the placebos. They will not know which study products you are getting, and neither will you. Only the pharmacist at your site will have this information while the study is going on.

You will have to wait until everyone completes their final study visits to find out what study products you got. This could be 2-5 years. But, if you have a serious medical problem and need to know what you got before the end of the study, we can tell you.

12. We will give you the study products on a schedule.

There are 4 groups in this study. Each group will get a different combination of study products. The group you get assigned to is completely random. Each group will get 8 injections during the study. You will get the injections into your upper arms. At some visits you will get one injection. At other visits, you will get 3 injections.

The ALVAC vaccine or its placebo will go into the left arm. The Protein/MF59 vaccine and Protein/AS01$_B$ vaccine and their placebos will go into the right arm.

Site: You may insert the picture version of the injection schedule (Appendix I) in place of (or in addition to) the text version or give it as a separate document to volunteers if you believe it will be helpful to them. You are not required to do either.

Group	Number of people	Protein dose	Arm	First injection visit	Time after first injection visit: 1 month	3 months	6 months
1	50	High dose	Left	ALVAC-HIV	ALVAC-HIV	ALVAC-HIV	ALVAC-HIV
			Right			Protein/MF59 + Placebo	Protein/MF59 + Placebo
2	50	High dose	Left	ALVAC-HIV	ALVAC-HIV	ALVAC-HIV	ALVAC-HIV
			Right			Protein/AS01$_B$ + Placebo	Protein/AS01$_B$ + Placebo
3	50	Low dose	Left	ALVAC-HIV	ALVAC-HIV	ALVAC-HIV	ALVAC-HIV
			Right			Protein/AS01$_B$ + Placebo	Protein/AS01$_B$ + Placebo
4	10	N/A	Left	Placebo	Placebo	Placebo	Placebo
			Right			Placebo + Placebo	Placebo + Placebo

You will have to wait in the clinic for about a half hour after each set of injections to see if there are any problems. Then for that night and for 7 more days, you will need to keep track of how you are feeling and if you have any symptoms. Within 3 days of vaccination, we will ask you to contact us or clinic staff will contact you to check on how you are doing. You should always contact us if you have any issues or concerns after receiving an injection. If you have a problem, we will continue to check on you until it goes away.

13. In addition to giving you the study products, we will:

- Do regular HIV testing, as well as counseling on your results and on how to avoid getting HIV;
- Do physical exams;
- Do pregnancy tests if you were assigned female sex at birth;
- Ask questions about your health, including medications you may be taking;
- Ask questions about any personal problems or benefits you may have from being in the study, and;
- Take blood and urine samples.

Each time we take blood, the amount will depend on the lab tests we need to do. It will be some amount between 10 mL and 200 mL (2 teaspoons to a little less than 1 cup/ 14 tablespoons). Your body will make new blood to replace the blood we take out.

Site: You may want to add a sentence to the end of the previous paragraph contextualizing the blood volumes described (eg, "To compare, people who donate blood in the US can give a total of about 500 mL in an 8-week period."). Modify the example for cultural relevance and alter blood volumes as necessary.

Site: Insert Appendix D, Table of procedures (for informed consent form) in this section or distribute it as a separate sheet if it is helpful to your study participants. You are not required to do either.

We will be looking for side effects. We will review the results of these procedures and tests with you at your next visit, or sooner if necessary. If any of the results are important to your health, we will tell you.

Site: in the following section, delete references to semen if your site is not participating in semen collection.

14. If you agree, we will also collect stool, rectal fluid and cervical fluid or semen.

At the end of this form we will ask if you allow us to collect stool, rectal fluid and cervical fluid (if you were assigned female sex at birth) or semen (if you were assigned male at birth). You can decide not to give any of these samples and still be in the study.

Stool

We would like to collect a small sample of your stool to look at the bacteria living in your stomach. We want to learn if your immune response to the study vaccines is influenced by these bacteria. We will do this twice during this study. If you agree to give the rectal fluid sample described below, we can collect the stool sample at that time, or you may provide a stool sample at home or at the clinic. The clinic must receive the stool sample within 24 hours after it is collected.

Rectal fluid, cervical fluid, or semen

We want to see how the study vaccines affect the parts of the body where people may be exposed to HIV: their rectum, vagina, and penis.

We would like to collect these samples at 3 visits. When we collect the samples, we will test you for gonorrhea, chlamydia and syphilis. If you were assigned female sex at birth, we will also test you for pregnancy, trichomoniasis, bacterial vaginosis and if needed, for a yeast infection. We will explain what these tests are for and we will give you the results. If you need care, we will tell you about the care we can give you at the clinic. We will also tell you about care we can help you get elsewhere. We will ask you to avoid some activities for 2 days before we collect these samples. This will help make sure your samples give accurate lab readings.

Rectal fluid

Site: You may delete the units of measure that are not used at your site in the next sentence. We will collect rectal fluid by first inserting a plastic tube into your rectum that is about 10 cm (4 inches) long and a little less than 2.5 cm (1 inch) wide. The tube will go inside your bum about 7 cm (3 inches). Then we will insert up to 3 small absorbent sponges through the tube into the rectum. The sponges will be left in place for 5 minutes and then removed.

For the 2 days before we collect your rectal fluid:

- Do not have receptive anal intercourse
- Do not put anything into your anus, including cleaning products (creams, gels, lotions, pads, etc.), lubricant, enemas or douches (even with water)
- Do not use any anti-inflammatory creams in or around your anus.

We will not collect rectal fluid if we learn that you are pregnant, or if we think you may have an anal or rectal infection. You should tell us if your rectal area is sore.

Cervical fluid

If you are 21 or older, you must have had a Pap smear within the last 3 to 5 years with the most recent result being normal. If you have not had a Pap smear within the last 3 years and would like to get one, we will tell you where you can get one. If you are younger than 21, you do not need a Pap smear because at that age it is not medically necessary.

To collect cervical fluid, we will give you a menstrual cup to insert into your vagina. The study staff will explain how to insert and remove the cup, or they can do it for you at the clinic. We will explain how many cups we will collect and how long you should wear them.

For the 2 days before we collect your cervical fluid,

- Do not use any spermicide, lubricants, douche (even with water), or medication in or around your vagina;
- Do not have vaginal intercourse or insert anything into your vagina.

Do not insert the menstrual cup:

- if you think you may be pregnant.
- if you think you may have a cervical or vaginal infection. We may ask you to collect this sample at a later date.

Semen

You may provide the semen at home or here. We will give you a plastic cup and ask you to ejaculate into it. We must receive the semen sample within 2 hours or less after it is collected. For at least 2 days before providing the semen, we will ask you:

- **not** to have sex, including oral sex
- **not** to ejaculate
- **not** to use anything with lubricants
- **not** to put saliva on the penis

You should tell us if you think you have an infection on your penis. If you have an infection, we may not use your sample.

15. The HVTN will test your samples to see how your immune system responds to the study products.

We will send your samples (without your name) to labs approved by the HVTN for this study, which are located in the United States and South Africa. Researchers at these labs will test your samples to see how your immune system responds to the study products. In rare cases, some of your samples may be sent to labs approved by the HVTN in other countries for research related to this study.

Researchers may also do genetic testing related to this study on your samples. Your genes are passed to you from your birth parents. They affect how you look and how your body works. The differences in people's genes can help explain why some people get a disease while others do not. The genetic testing will only involve some of your genes, not all of your genes (your genome). The researchers will study only the genes related to the immune system and HIV and those that affect how people get HIV.

If you become HIV infected, the researchers may look at all of the genes of the virus found in your samples. If you give cervical, stool, or rectal fluid samples, the researchers may look at all of the genes of the bacteria found in your samples. In both cases the researchers will use this information to learn more about HIV and the study product(s). The researchers may put this information about the virus and/or bacteria into a protected database so that other researchers can access it. They would not be able to link the information to you.

In some cases, researchers may take cells from your samples and grow more of them over time, so that they can continue to contribute to this study.

Tests done on your samples are for research purposes, not to check your health. The labs will not give the results to you or this clinic because their tests are not approved for use in making health care decisions.

When your samples are no longer needed for this study, the HVTN will continue to store them.

16. We will counsel you on avoiding HIV infection.

We will ask you personal questions about your HIV risk factors such as sexual behavior, alcohol, and drug use. We will talk with you about ways to keep your risk of getting HIV low.

Site: Delete next section if using separate consent for use of samples and information in other studies.

17. When samples are no longer needed for this study, the HVTN wants to use them in other studies and share them with other researchers. The HVTN calls these samples "extra samples."

The HVTN will only allow your extra samples to be used in other studies if you agree to this. You will mark your decision at the end of this form. If you have any questions, please ask.

Do I have to agree? No. You are free to say yes or no, or to change your mind after you sign this form. At your request, we will destroy all extra samples that we have. Your decision will not affect your being in this study or have any negative consequences here.

Where are the samples stored? Extra samples are stored in a secure central place called a repository. *[Site: choose one of the following two sentences. African sites should choose the sentence referencing the repository in South Africa. All other sites should choose the sentence referencing the repository in the United States.]* Your samples will be stored in the HVTN repository in South Africa. Your samples will be stored in the HVTN repository in the United States.

How long will the samples be stored? There is no limit on how long your extra samples will be stored. *[Site: Revise the previous sentence to insert limits if your regulatory authority imposes them.]*

Will I be paid for the use of my samples? No. Also, a researcher may make a new scientific discovery or product based on the use of your samples. If this happens, there is no plan to share any money with you. The researcher is not likely to ever know who you are.

Will I benefit from allowing my samples to be used in other studies? Probably not. Results from these other studies are not given to you, this clinic, or your doctor. They are not part of your medical record. The studies are only being done for research purposes.

Will the HVTN sell my samples and information? No, but the HVTN may share your samples with HVTN or other researchers. Once we share your samples and information, we may not be able to get them back.

How do other researchers get my samples and information? When a researcher wants to use your samples and information, their research plan must be approved by the HVTN. Also, the researcher's institutional review board (IRB) or ethics committee (EC) will review their plan. *[Site: If review by your institution's IRB/EC/RE is also required, insert a sentence stating this.]* IRBs/ECs protect the rights and well-being of people in research. If the research plan is approved, the HVTN will send your samples to the researcher's location.

What information is shared with HVTN or other researchers? The samples and information will be labeled with a code number. Your name will not be part of the information. However, some information that we share may be personal, such as your race, ethnicity, sex, health information from the study, and HIV status. We may share information about the study product you received and how your body responded to the study product.

What kind of studies might be done with my extra samples and information? The studies will be related to HIV, vaccines, the immune system and other diseases.

Researchers may also do genetic testing on your samples.

In some cases, researchers may take cells from your samples and grow more of them over time, so that they can continue to do research with them.

If you agree, your samples could also be used for genome-wide studies. In these studies, researchers will look at all of your genes (your genome). The researchers compare the genomes of many people, looking for common patterns of genes that could help them understand diseases. The researchers may put the information from the genome-wide studies into a protected database so that other researchers can access it, but your name and other personal information will not be included. Usually, no one would be able to look at your genome and link it to you as a person. However, if another database exists that also has information on your genome and your name, someone might be able to compare the databases and identify you. If others found out, it could lead to discrimination or other problems. The risk of this is very small. There may be other unknown risks.

Who will have access to my information in studies using my extra samples?

People who may see your information are:

- Researchers who use your extra samples and information for other research
- Government agencies that fund or monitor the research using your extra samples and information

- Any regulatory agency that reviews the research using your extra samples and information

- The researcher's Institutional Review Board or Ethics Committee

- The people who work with the researcher

All of these people will do their best to protect your information. The results of any new studies that use your extra samples and information may be published. No publication will use your name or identify you personally.

18. We will do our best to protect your private information.

US sites: Check HIPAA authorization for conflicts with this section.

Your study records and samples will be kept in a secure location. We will label all of your samples and most of your records with a code number, not your name or other personal information. However, it is possible to identify you, if necessary. We will not share your name with the lab that does the tests on your samples, or with anyone else who does not need to know your name.

Sites: Any change to the following highlighted text requires approval from HVTN Regulatory Affairs

We do need to share your name with the HVTN in case you need proof in the future that you participated in an HIV vaccine study. The HVTN will keep your name in a secure file with these items:

- The name of your study

- Your age or date of birth

- Your study ID number

- What study product(s) you received

There are no HIV test results kept in this file. The HVTN will not share any information that could identify you without your agreement. The HVTN will remove your name from the file if you do not want it there.

Clinic staff will have access to your study records. Your records may also be reviewed by groups who watch over this study to see that we are protecting your rights, keeping you safe, and following the study plan. These groups include:

- The US National Institutes of Health, its study monitors, and its chosen representatives,

- The US Food and Drug Administration,

- Any regulatory agency that reviews clinical trials,
- [Insert name of local IBC],
- [Insert name of local IRB/EC] ,
- [Insert name of local and/or national regulatory authority as appropriate],
- GlaxoSmithKline Biologicals S.A., Sanofi Pasteur and people who work for them,
- The HVTN and people who work for them,
- The HVTN Safety Monitoring Board; and
- The US Office for Human Research Protections.

All reviewers will take steps to keep your records private.

We cannot guarantee absolute privacy. At this clinic, we have to report the following information:

Site: Include any public health or legal reporting requirements. Bulleted examples should include all appropriate cases (reportable communicable disease, risk of harm to self or others, etc.).

- [Item 1]
- [Item 2]
- [Item 3]

US sites: Include the following boxed text. You can remove the box.

We have a Certificate of Confidentiality from the US government, to help protect your privacy. With the certificate, we do not have to release information about you to someone who is not connected to the study, such as the courts or police. Sometimes we can't use the certificate. Since the US government funds this research, we cannot withhold information from it. Also, you can still release information about yourself and your study participation to others.

The results of this study may be published. No publication will use your name or identify you personally.

We may share information from the study with other researchers. We will not share your name or information that can identify you.

Sites: The text below may not be deleted or changed, per FDA requirement. It's OK to remove the box around it.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

19. We may stop your injections or take you out of the study at any time. We may do this even if you want to stay in the study and even if you were scheduled for more injections.

This may happen if:

- you do not follow instructions,
- we think that staying in the study might harm you,
- you get HIV,
- you enroll in a different research study where you get another study product, or
- the study is stopped for any reason.

If we stop your injections, we may ask you to stay in the study to complete other study procedures.

20. We will stop your injections if you become pregnant before your last injection.

We will encourage you to stay in the study if you choose. We will discuss your study options with you.

If you leave the study while you are still pregnant, we will contact you after your due date to ask some questions about your pregnancy and delivery.

21. If you get infected with HIV during the study, we will stop your injections, take fewer samples, and help you get care and support.

We will encourage you to stay in this study for up to 6 months after your last study product administration if you choose. We will discuss your study options with you. We will counsel you about your HIV infection and about telling your partner(s). We will tell you where you can get support and medical care. *Site: Modify the following sentence as appropriate.* We will not provide or pay for any of your HIV care directly.

Other Risks

22. There are other risks to being in this study.

This section describes the other risks and restrictions we know about. There may also be unknown risks, even serious ones. We will tell you if we learn anything new that may affect your willingness to stay in the study.

Risks of routine medical procedures:

In this study, we will do some routine medical procedures. These are taking blood and giving injections. These procedures can cause bruising, pain, fainting, soreness, redness, swelling, itching, a sore, bleeding, and (rarely) muscle damage or infection where you got the injection. Taking blood can cause a low blood cell count (anemia), making you feel tired.

Risks of collecting rectal and cervical fluids:

You may have some discomfort and minor bleeding during these procedures. This does not usually last very long.

Personal problems/discrimination/testing HIV antibody positive:

About 10 to 20% of people who join HVTN studies report personal problems or discrimination because of joining an HIV vaccine study. Family or friends may worry, get upset or angry, or assume that you are infected with HIV or at high risk and treat you unfairly as a result. Rarely, a person has lost a job because the study took too much time away from work, or because their employer thought they had HIV.

The body makes antibodies to fight or prevent infection. Most vaccines cause the body to make antibodies as a way of preventing infection. Your body may make antibodies to HIV because you received HIV study vaccines. The study vaccines are likely to cause you to test positive on some types of HIV tests, even if you are not infected with HIV. This is called vaccine-induced seropositivity (VISP). VISP means that after you get the study vaccines, a routine HIV test done outside this clinic is likely to say you have HIV, even if you don't. For this reason, you should plan to get HIV tests only at this clinic during the study. Our tests can tell the difference between true HIV infection and a positive result that is caused by the study vaccines.

If you receive a positive test result caused by the study vaccines at any time, we can arrange free HIV testing for as long as you need it. If this happens, we do not know how long you will test positive due to the study vaccines. If you receive a positive HIV test result and we determine it is because you have HIV, we will refer you for follow-up care.

It is unlikely, but you could test negative at the end of the study and positive some time later, even though you don't have HIV. This could happen if different HIV tests come into use. We will give you a phone number to call for more information.

Site: Modify the following paragraph if applicable. If someone believes you are infected with HIV even if you are not, you could face discrimination and other problems. For example, you could be denied medical or dental care, employment, insurance, a visa, or entry into the military in some countries. If you do have a positive HIV antibody test caused by the study vaccines, you will not be able to donate blood or organs. Your family and friends may treat you differently. We will give you a brochure that tells you more about testing HIV positive because of an HIV vaccine, and how you can avoid some of these problems.

If you become pregnant during or after the study and have VISP, we don't know if the antibodies could be passed to your baby. We know that this happens with other vaccines, like tetanus vaccine. These antibodies from the mother are not a danger to the baby, and they go away over time. For most babies antibodies from the mother last for about six months.

You should always tell the delivery staff if you have VISP. However, you may still be tested for HIV using the antibody test when you deliver your baby. If your test is positive and the delivery staff believes you have an HIV infection, your baby may be started on antiretroviral treatment when it is not needed. If this happens, we can arrange for you and the baby to have a test that can tell the difference between true HIV infection and a VISP result. If you or the baby continue to have VISP, we can arrange this testing for free for as long as it is needed.

Embarrassment/anxiety:

You may feel embarrassed when we ask about your HIV risks, such as having sex and using drugs. Also, waiting for your HIV test results or other health test results could make you feel anxious. You could feel worried if your test results show that you are infected with HIV. If you feel embarrassed or anxious, please tell us and we will try to help you.

Risks of disclosure of your personal information:

We will take several steps to protect your personal information. Although the risk is very low, it is possible that your personal information could be given to someone who should not have it. If that happened, you could face discrimination, stress, and embarrassment. We can tell you more about how we will protect your personal information if you would like it.

Risks of genetic testing:

It is unlikely, but the genetic tests done on your samples could show you may be at risk for certain diseases. If others found out, it could lead to discrimination or other problems. However, it is almost impossible for you or others to know your test results from the genetic testing. The results are not part of your study records and are not given to you.

U.S. Sites, include the following paragraph. In the very unlikely event that your genetic information becomes linked to your name, a federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect you. GINA keeps health insurance companies and employers from seeing results of genetic testing when deciding about giving you health insurance or offering you work. GINA does not help or protect you against discrimination by companies that sell life, disability or long-term care insurance.

Unknown risks:

We do not know if the study vaccines will increase, decrease, or not change your risk of becoming infected with HIV if exposed. If you get infected with HIV, we do not know how the study vaccines might affect your HIV infection or how long it takes to develop AIDS.

We do not know if getting these study vaccines will affect how you respond to any future approved HIV vaccine. Currently, no HIV vaccine has been approved for use.

We do not know how the study vaccines will affect a pregnant participant or a developing baby.

Benefits

23. The study may not benefit you.

We do not know whether getting the study vaccines might benefit you in any way. However, being in the study might still help you in some ways. The counseling that you get as part of the study may help you avoid getting HIV. The lab tests and physical exams that you get while in this study might detect health problems you don't yet know about.

This study may help in the search for a vaccine to prevent HIV. However, if the study vaccines later become approved and sold, there are no plans to share any money with you.

Your rights and responsibilities

24. If you join the study, you have rights and responsibilities.

You have many rights that we will respect. You also have responsibilities. We list these in the Participant's Bill of Rights and Responsibilities. We will give you a copy of it.

Leaving the study

25. Tell us if you decide to leave the study.

You are free to leave the study at any time and for any reason. Your care at this clinic and your legal rights will not be affected, but it is important for you to let us know.

We will ask you to come back to the clinic one last time for a physical exam, and we may ask to take some blood and urine samples. We will also ask about any personal problems or benefits you have experienced from being in the study. We believe these steps are important to protecting your health, but it is up to you whether to complete them.

Injuries

Sites: Do not change text in the following section (except as prompted) without obtaining prior approval from HVTN Regulatory Affairs at vtn.core.reg@hvtn.org

26. If you get sick or injured during the study, contact us immediately.

Your health is important to us. *(Sites: adjust the following 2 sentences if applicable to the care available at your site)* We will tell you about the care that we can give you here. For the care that we cannot provide, we will explain how we will help you get care elsewhere.

If you become sick or injured in this study, there is a process to decide if it is related to the study products and/or procedures. If it is, we call it a study-related injury. There are funds to pay for treatment of study-related injuries if certain conditions are met.

Next paragraph for African sites:

Sites: adjust the language in this paragraph so it is applicable to your site. Note: insurance is purchased for all African countries. In this study, our clinic has insurance to cover your medical treatment in the case of a study-related injury. In rare cases, the insurance funds may not be enough. The vaccine developers have agreed to pay medical costs for study-related injuries that are determined to be caused by their own study products.

The HVTN has limited funds to pay medical costs that it determines are reasonable. *(Sites: insert locale-appropriate medical insurance language in the following sentence)* If the injury is not study related, then you and your health insurance will be responsible for treatment costs.

Some injuries are not physical. For example, you might be harmed emotionally by being in an HIV vaccine study. Or you might lose wages because you cannot go to work. However, there are no funds to pay for these kinds of injuries, even if they are study related.

You may disagree with the decision about whether your injury is study related. If you wish, the HVTN will ask independent experts to review the decision. You always have the right to use the court system if you are not satisfied.

Questions

27. If you have questions or problems at any time during your participation in this study, use the following important contacts.

If you have questions about this study, contact
[name and telephone number of the investigator or other study staff].

If you have any symptoms that you think may be related to this study, contact
[name and telephone number of the investigator or other study staff].

If you have questions about your rights as a research participant, or problems or concerns about how you are being treated in this study, contact
[name/title/phone of person on IRB or other appropriate organization].

If you want to leave this study, contact
[name and telephone number of the investigator or other study staff].

Your permissions and signature

28. In section 14 of this form, we told you about collecting stool, rectal fluid and cervical fluid or semen. Please write your initials or make your mark in the boxes next to the options you choose.

☐ I agree to provide stool samples.

☐ I do not agree to provide stool samples.

☐ I agree to provide rectal fluid.

☐ I do not agree to provide rectal fluid.

For people assigned female sex at birth:

☐ I agree to provide cervical fluid.

☐ I do not agree to provide cervical fluid.

☐ N/A: assigned male sex at birth

Site: Delete the following if your site is not participating in semen collection

For people assigned male sex at birth:

☐ I agree to provide semen.

☐ I do not agree to provide semen.

☐ N/A: assigned female sex at birth

Site: Delete this section if using a separate consent for use of samples and information in other studies

29. In Section 17 of this form, we told you about possible other uses of your extra samples and information, outside this study. Please choose only one of the options below and write your initials or make your mark in the box next to it. Whatever you choose, the HVTN keeps track of your decision about how your samples and information can be used. You can change your mind after signing this form.

☐ I allow my extra samples and information to be used for other studies related to HIV, vaccines, the immune system, and other diseases. This may include genetic testing and keeping my cells growing over time.

OR

☐ I agree to the option above *and* also to allow my extra samples and information to be used in genome wide studies.

OR

☐ I do not allow my extra samples to be used in any other studies. This includes not allowing genetic testing, growing more of my cells, or genome wide studies.

30. If you agree to join this study, you will need to sign or make your mark below. Before you sign or make your mark on this consent form, make sure of the following:

- You have read this consent form, or someone has read it to you.
- You feel that you understand what the study is about and what will happen to you if you join. You understand what the possible risks and benefits are.
- You have had your questions answered and know that you can ask more.
- You agree to join this study.

You will not be giving up any of your rights by signing this consent form.

Participant's name (print)	Participant's signature or mark	Date	Time

Clinic staff conducting consent discussion (print)	Clinic staff signature	Date	Time

For participants who are unable to read or write, a witness should complete the signature block below:

Witness's name (print)	Witness's signature	Date	Time

*Witness is impartial and was present for the entire discussion of this consent form.